

MECLIZINE HCL 25 MG- meclizine hydrochloride tablet, chewable

Unit Dose Services

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Meclizine HCl 25 mg Chewable Tablets

Active ingredient (in each chewable tablet)

Meclizine HCl, USP 25 mg

Purpose

Antiemetic

Uses

prevents and treats nausea, vomiting or dizziness due to motion sickness

Warnings

Do not use in children under 12 years of age unless directed by a doctor.

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

If pregnant or breast-feeding, ask a health professional before use

Keep out of reach of children.

In case of overdose, get medical help or contact the poison control center immediately.

Directions

- Dosage should be taken one hour before travel starts.
- **Adults and children 12 years of age and older:** Chew 1-2 tablets once daily or as directed by a doctor
- **Children under 12 years:** do not give this product to children under 12 years of age unless directed by a doctor.

Other information

- store at room temperature
- Phenylketonurics: Contains phenylalanine 0.28 mg per tablet
- **Do not use if imprinted safety seal under cap is broken or missing**

Inactive ingredients

aspartame, croscarmellose sodium, dextrose, FD&C Red #40 Lake, magnesium stearate, maltodextrin,

microcrystalline cellulose, natural and artificial flavors, silicon dioxide, sodium sulfate, sugar, tricalcium phosphate.

Questions or comments?

If you have any questions or comments or to report an adverse event, please contact **(800) 795-9775**.


Distributed by: Plus Pharma, Commack, NY 11725

*Plus Pharma is not affiliated with the owner of the registered trademark Bonine®.

When using this product

- may cause drowsiness
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- use caution when driving a motor vehicle or operating machinery

MECLIZINE HCL 25 MG (MECLIZINE HYDROCHLORIDE) TABLET, CHEWABLE

MECLIZINE HCL (ANTIEMETIC) 25 MG / 30 CHEWABLE TABS Treats & Prevents Motion Sickness NDC: 50436-0994-1 RASPBERRY Dist. by: Plus Pharma, Commack, NY 11725 Pkg. by: Unit Dose Services, Dania, FL 33004		OTHER INFORMATION* Phenylketonurics: Contains Phenylalanine 0.28 mg per tablet * Store at room temperature INACTIVE INGREDIENTS: aspartame, croscarmellose sodium, dextrose, FD&C Red #40 Lake, magnesium stearate, maltodextrin, microcrystalline cellulose, natural and artificial flavors, silicon dioxide, sodium sulfate, sugar, tricalcium phosphate. IF PREGNANT OR BREAST-FEEDING, ask a health professional before use. KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical help or contact the poison control center immediately.	
Prevents nausea, dizziness, and vomiting Rev. 1 DRUG FACTS Active Ingredient (in each chewable tablet) Meclizine HCL, USP 25mg Uses: Prevents and treats nausea, vomiting, or dizziness due to motion sickness Warnings: Do not use in children under 12 years of age unless directed by a doctor Ask a doctor before use if you have* Glaucoma *A breathing problem such as emphysema or chronic bronchitis * Trouble urinating due to an enlarged prostate gland Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers. When using this product* May cause drowsiness * Alcohol, sedatives, and tranquilizers may increase drowsiness * Avoid alcoholic drinks * Use caution when driving a motor vehicle or operating machinery	Purpose Antiemetic DIRECTIONS: Dosage should be taken one hour before travel starts * Adults and children 12 years of age and older: Chew 1-2 tablets once daily, or as directed by a doctor * Children under 12 years: do not give this product to children under 12 years of age unless directed by a doctor Do not use if imprinted safety seal under cap is broken or missing	 LOT # XXXXXXXX EXP: XX/XX/XX MFG NDC: 51645-994-10 MFG LOT # XXXXXXXX	
		NDC: 50436-0994-1 Meclizine HCL Lot # XXXXXXXX	25mg/30 Chew Tabs Exp: XX/XX/XX
		NDC: 50436-0994-1 Meclizine HCL Lot # XXXXXXXX	25mg/30 Chew Tabs Exp: XX/XX/XX

MECLIZINE HCL 25 MG

meclizine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50436-0994(NDC:51645-994)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
SUCROSE (UNII: C151H8M554)	

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

Product Characteristics			
Color	pink (Uncoated)	Score	2 pieces
Shape	ROUND (Biconvex)	Size	8mm
Flavor	RASPBERRY	Imprint Code	21G
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-0994-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	10/15/2015	

Labeler - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-0994) , RELABEL(50436-0994)

Revised: 12/2017

Unit Dose Services